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Display Date 9-27-05
Publication Date 9-28-05
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–05–3000]

Memorandum of Understanding Between the Food and Drug Administration and the National Library of Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration and the National Library of Medicine (NLM). The purpose of this MOU is to assign responsibilities to FDA's Center for Drug Evaluation and Research (CDER) and NLM for the distribution of product labeling.

DATES: The agreement became effective July 6, 2005, and supplements the agreement signed and dated November 21, 2001, and December 3, 2001, by NLM and CDER representatives, respectively.

FOR FURTHER INFORMATION CONTACT:

For FDA: Lisa Stockbridge, Food and Drug Administration (HFD–140), 5600 Fishers Lane, Rockville, MD 20857, 301–827–7761; or Catherine Miller, Food and Drug Administration (HFD–140), 5600 Fishers Lane, Rockville, MD 20857, 301–827–7772.

For NLM: Simon Liu, Bldg. 38A, rm. 2N221, 8600 Rockville Pike, Bethesda, MD 20894, 301–402–1698; or Stuart Nelson, Bldg. 38A, rm. B2E17, 8600 Rockville Pike, Bethesda, MD 20894, 301–496–1495.

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SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: SEP 2 0 2005

September 20, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[INSERT MOU]

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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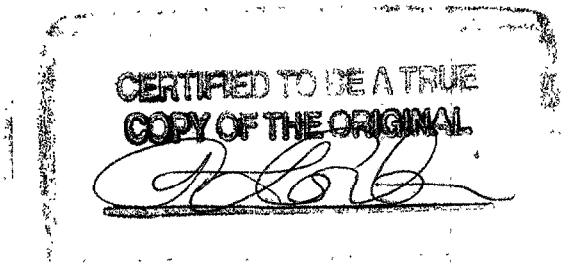

Memorandum of Understanding between the National Library of Medicine and the Food and Drug Administration

I. Purpose

The purpose of this agreement is to assign responsibilities to the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) and the National Library of Medicine (NLM) for the distribution of product labeling. This agreement supplements the agreement signed and dated November 21 and December 3, 2001, by NLM and CDER representatives, respectively.

II. Background

This agreement is needed to ensure that the content of product labeling, such as the physician's insert of prescription drug labels, is readily available to health information providers and the public in its most up-to-date form as part of the *DailyMed Initiative*. The *DailyMed Initiative* is a partnership between the FDA, the Veterans Administration (VA), the National Library of Medicine (NLM), medication manufacturers and distributors, and healthcare information suppliers. Medication manufacturers and distributors will collaborate with the FDA to maintain detailed information about their products in a machine-readable format called Structured Product Labeling (SPL). SPL is structured information about a medication contained in an XML file. Any new or changed SPL for a product will be transmitted from the CDER to the NLM each business day. NLM will maintain the up-to-date SPL in an electronic repository called the *DailyMed*. Information from this repository will be accessible for download at no cost from a publicly available web site. Healthcare information suppliers will be able to use the SPL from this repository in their computer systems, allowing providers and patients access to reliable, up-to-date information on the medications they use.

The NLM currently has considerable information about pharmaceuticals, both naming information as well as published literature, but the availability of the content of labeling assists in fulfilling the NLM mission.

III. Substance of Agreement and Responsibilities of Each Agency

The CDER agrees to transmit new or changed SPL for a product each business day. The NLM agrees to make the transmitted SPL available the next business day for download by the public at no cost. The transmittal of SPL for approved human prescription drugs will begin following implementation of the CDER Electronic Labeling Information Processing System planned for October 2005. Subsequent transfers of SPL for over-the-counter and other regulated human drug products will begin within 18 months of the initial implementation for approved human prescription drugs. The CDER will transmit only those SPL it deems acceptable for posting; however, in the event of an error, the CDER may notify the NLM to refrain from posting one or more SPL files from a transmission that has been received but not yet posted to the *DailyMed*. The CDER and NLM databases will be synchronized annually on April 1 (or the next business day), or as needed. The CDER will transmit all currently available SPL to the NLM. In addition, the NLM will post the following disclaimer in a prominent location at the point-of-entry to the *DailyMed* website, "The labeling on this website is the most recent submitted to the FDA and currently in use, and may include strengthened warnings undergoing FDA review and minor editorial changes." Until legacy data has been completely rendered into SPL, the website will also display the disclaimer, "This website does not contain a complete listing of labeling for approved prescription drugs."

As indicated, the FDA is the provider and the NLM is the recipient of SPL. Per this agreement, the NLM is not responsible for the content of the SPL as long as the received SPL is posted in its unaltered state. In order to ensure the SPL is received from an authorized source, the FDA and the NLM further agree to the following:

A. The FDA shall transmit the SPL to a NLM designated server via an existing HHS network using a previously agreed form of electronic signature.

B. The NLM shall receive and process SPL only after the electronic signature has been verified to be correct.

C. After each daily processing, the NLM shall send the FDA a summary of the transmission for verification purposes.

IV. Name and Address of Participating Parties:

A. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

B. National Library of Medicine
National Institute of Health
8600 Rockville Pike
Bethesda, Maryland 20894

V. Liaison Officers

A. Contacts for the FDA

a) Lisa Stockbridge, PhD
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(301) 827-7761

b) Catherine Miller
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B. Contacts for the NLM

a) Dr. Simon Liu
Director, Information Systems
Bldg 38A, Room 2N221
8600 Rockville Pike
Bethesda, MD 20894
(301) 402-1698

b) Stuart Nelson, MD
Head, Medical Subject Headings
Building 38A Room B2 E17
8600 Rockville Pike
(301) 496-1495

VI. Period of Agreement

The agreement becomes effective upon signature of both parties and will continue without expiration. It may be modified by mutual consent or terminated by either party upon 120 days written notice.

APPROVED AND ACCEPTED FOR THE NATIONAL LIBRARY OF MEDICINE

By Betsy L. Humphreys

Betsy Humphreys
Deputy Director
National Library of Medicine

Date 6/23/2005

APPROVED AND ACCEPTED FOR THE CENTER FOR DRUG EVALUATION AND RESEARCH

By

Janet Woodcock, MD (Acting)
Deputy Commissioner for Operations
Office of the Commissioner

Date 7/06/05